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REVIEW

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¶1. (SBU) SUMMARY. Mission Germany recommends that Germany receive the same treatment in the 2007 301 Report as it received in 2006 and not be listed in the priority watch list category. The situation facing American pharmaceutical companies in Germany has not appreciably deteriorated during the past year. The German government is currently implementing a wide-scale health care reform. It is too early to evaluate how this reform will impact American pharmaceutical companies, and unfair to prejudge this legislation before it is implemented. An amendment to the law on pharmaceutical reference pricing system was passed in 2006, addressing some industry concerns about disparate treatment for generic and patented pharmaceuticals. The amendment attempted to clarify the procedure by which drugs can be listed as innovative. U.S. industry maintains that Germany's reference pricing system continues to unfairly discriminate against U.S. companies. While we remain concerned about the government's referenced pricing system and its impact on U.S. industry we are improving our dialogue with the German government to educate them regarding the impact of these regulations on the pharmaceutical sector and the role of innovation in Germany. We believe this dialogue is bearing fruit and the situation has not appreciably deteriorated over the past year to warrant Germany's placement on the priority watch list. END SUMMARY.

¶2. (SBU) PhRMA's Special 301 submissions for 2006 and 2007 are very similar, reflecting the fact that the situation for PhRMA in Germany has not appreciably changed during the past year. PhRMA raises concerns about the impact of pending health care reform legislation. However, post deems it inappropriate to judge the German government on legislation that has not yet been implemented and whose impact on the pharmaceutical industry remains unclear.

¶3. (SBU) During the past year, the German government passed the Health Cost Containment Act, which did address some of PhRMA's concerns. The act, which went into effect on April 1, was the first major amendment to the Fixed Referenced Priced System instituted in 2004 and clarifies the process for deciding which drugs are truly innovative, and thus exempt from reference pricing. For the first time, it also imposes a mandatory 10% rebate on generics, which will affect mainly German manufacturers and addresses PhRMA's complaint that the law unfairly favors generic drugs (mainly of German origin) at the expense of patented drugs (mainly of U.S. origin). The law also requires the government to develop rules clearly defining innovative drugs. These rules are

intended to make the process for declaring which drugs are innovative more reliable and transparent. While the amendment also contained measures criticized by industry, we believe it is an attempt by the government to address industry concerns and try to improve legislation on reference pricing. We have asked industry to document their concerns over specific decisions of the Joint Federal Committee of Doctors and Sick Funds and inform of the Embassy of any applications for innovative drugs that were denied. During the past year, we have received no such information from any member of PhRMA.

¶4. (SBU) The Embassy has continued to engage with the German government on the need for transparency in the process of determining innovative drugs. Deputy Secretary of Health and Human Services Alex Azar visited Germany in February 2006 and met with German officials and industry to discuss the need for innovation in the pharmaceutical sector. The Ambassador and other USG officials have met repeatedly with the officials from the ministries of Health and Economics to discuss our concerns. German Health Minister Schmidt traveled to the U.S. several times in 2006 to gather more information on the U.S. approach to cost containment and innovation in the health care sector. USTR is proposing to head a delegation in the spring of 2007 to visit Germany to continue this dialogue.

¶5. (SBU) We have continue to concerns regarding the impact of the German reference pricing system for pharmaceuticals on U.S. industry. But we believe that placing Germany onthe priority watch list could have a damaging impact on our ongoing discussions with Germany on the need to foster a climate for innovation in the health care sector. The German government has addressed some industry concerns over the past

year. It is also up to industry to test the provisions of the amendment to the reference pricing system to see if Germany has made its system of declaring drugs innovative more transparent and fair. It also remains to be seen whether the impact of new health care legislation will be detrimental to the American pharmaceutical industry. Such concerns warrant further monitoring and a continued dialogue, not punitive measures.
TIMKEN JR